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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,818	12/07/2004	Junzo Tanaka	043070	5270
38834 7590 08/09/2007 WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP 1250 CONNECTICUT AVENUE, NW SUITE 700 WASHINGTON, DC 20036			EXAMINER NAFF, DAVID M	
			ART UNIT 1657	PAPER NUMBER
			MAIL DATE 08/09/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Office Action Summary</p>	Application No. 10/516,818	Applicant(s) TANAKA ET AL.	
	Examiner David M. Naff	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-15 is/are pending in the application.
- 4a) Of the above claim(s) 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/7/04, 1/26/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims in the application are 9-15.

A response of 5/9/07 to a restriction requirement of 4/9/07 elected Group I claims 9-14 without traverse.

5 Claim 15 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/9/07.

Claims examined on the merits are 9-14.

10 Document AA on 1449 of 12/7/04 has been lined through since the document is listed on 1449 of 1/26/05. Document AB on 1449 of 12/7/04 has been lined through since a copy has not been provided.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C.

15 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

20

Claims 9-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

25

Claim 9 is unclear as to the meaning and scope of "gradient of calcium phosphate". How does "gradient" define calcium phosphate in a composite having no structure?

Bridging lines 1 and 2 of claim 9, "one or more types of biodegradable polymeric materials" is uncertain as to meaning and scope. A "type" of polymeric material is relative and subjective.

In the last line of claim 9, "a composite thereof" is confusing
5 since no other material is set forth that can form a composite. It would be uncertain how this composite differs from the composite material of line 1 of the claim.

Claim 11 is unclear how the scaffold differs from the composite of claim 9 since the scaffold requires nothing different from the
10 composite, and can be only the composite material of claim 9.

Claim 12 is unclear how the scaffold required differs from the scaffold of claim 11 since claim 12 does not define additional structure or components of the scaffold. Claim 12 merely sets forth an intended function of the scaffold of claim 11.

15 Claim 13 is unclear how the implant differs from the composite of claim 9 since claim 13 requires no structure or components that would distinguish the implant from the composite. The implant can be only the composite of claim 9.

Claim Rejections - 35 USC § 103

20 The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

25 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any
5 evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art
10 under 35 U.S.C. 103(a).

Claims 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mattern et al (6,969,523) or Yannas et al (4,947,840) in view of Sherwood et al (6,454,811).

The claims are drawn to a composite material containing a
15 gradient of calcium phosphate in a biodegradable polymeric material selected from collagen and glycosaminoglycan, and a composite thereof.

Mattern et al (col 1, lines 11-30 and col 3, lines 50-67) and Yannas et al (paragraph bridging cols 1 and 2) disclose scaffolds formed of cross-linked collagen and glycosaminoglycan.

20 Sherwood et al disclose (col 4, lines 13-26 and 40-45) forming a gradient of calcium phosphate to provide a composite implantable device for regeneration of bone.

It would have been obvious to provide a gradient of calcium phosphate in the cross-linked collagen/glycosaminoglycan scaffold of

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Mattern et al or Yannas et al as suggested by Sherwood et al to make the scaffold suitable for bone regeneration.

Conclusion

Any inquiry concerning this communication or earlier


5 communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925.

10 The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


David M. Naff
Primary Examiner
Art Unit 1657

DMN

15 8/6/07